



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																								
Company Name: <input type="text" value="Zydus Pharmaceuticals USA Inc."/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="75-395"/>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allow s for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement (w rite in) <input type="text"/> <input type="checkbox"/> VII. No Requirement																																																								
Rx Product/Proprietary Name: <input type="text" value="Isosorbide Mononitrate Extended-Release Tablets, 60 mg 100s"/> NDC: <input type="text" value="68382-651-01"/> UPC: <input type="text" value="368382651013"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/>		b. Contact for temperature excursion questions: Name: <input type="text"/> Number: <input type="text"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>																																																								
Description: <input "60"="" and="" bisect="" n"="" on="" one="" other="" side="" side"="" the="" type="text" value="oval, yellow, film-coated tablets, debossed "/> Active ingredients: <input type="text" value="Isosorbide mononitrate"/> URL for Additional Product Information: <input type="text" value="www.zydususa.com"/>		c. Special regulations for product in certain states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/>																																																								
Address: <input type="text" value="73 Route 31 North"/> City: <input type="text" value="Pennington"/> State: <input type="text" value="NJ"/> Address 2: <input type="text"/> Key Contact: <input type="text"/> Email: <input type="text"/> Zip: <input type="text" value="08534"/> Phone Number: <input type="text" value="(609) 730 1900"/> Fax: <input type="text" value="(609) 730 1991"/>		d. Store product (unit of sale) upright? <input type="text" value="Yes"/> Protect product (unit of sale) from light? <input type="text" value="No"/>																																																								
FOR GENERIC DRUG PRODUCTS																																																										
I. Orange Book Rating: <input type="text" value="AB"/> II. Brand Name: <input type="text" value="Imdur"/> III. Generic Equivalent for Brand: <input type="text" value="Isosorbide Mononitrate Extended-Release Tablets, 60 mg 100s"/>		e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																																								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																										
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> DUNS: <input type="text" value="156861945"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: <input type="text"/> Other exemption - Write in: <input type="text"/>		c. Special regulations for product in certain states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/>																																																								
Is product repackaged? <input type="text" value="No"/> If Yes, was original product purchased direct from mfr? <input type="text" value="No"/> Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/> Are any waivers granted for product ID/barcode? <input type="text" value="No"/> If yes, attach documentation from FDA <input type="text"/>		d. Store product (unit of sale) upright? <input type="text" value="Yes"/> Protect product (unit of sale) from light? <input type="text" value="No"/>																																																								
ADDITIONAL PRODUCT INFORMATION			ITEM AND PACKING INFORMATION																																																							
Is the Product... Direct Ship Item <input type="text"/> Legend Device? <input type="text" value="No"/> State Control? <input type="text" value="No"/> ARCOS reportable? <input type="text" value="No"/> Co-Licensed? <input type="text" value="No"/> Controlled Substance? <input type="text" value="No"/> Schedule No.? <input type="text"/> (incl. N for non-narcotic) Controlled Substance Code: <input type="text"/> Hazardous Material/Cytotoxic Agent? <input type="text" value="No"/>		ORDER INFORMATION Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In <input type="text"/> What is the NDC selling unit? <input type="text" value="Each"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="Yes"/> If Yes, how many of which package type? <input type="text"/> Each <input type="text"/> Inner/ Carton/Pack <input type="text" value="1"/> Case		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>Item:</td> <td>42.29 g</td> <td></td> <td>3.23</td> <td>1.77</td> <td>5.7171</td> <td></td> </tr> <tr> <td>Box/ Carton:</td> <td></td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> <tr> <td>Case:</td> <td>2.3</td> <td>11.06</td> <td>4.18</td> <td>7.5</td> <td>346.731</td> <td>24</td> </tr> <tr> <td>Pallet:</td> <td></td> <td>48</td> <td>40</td> <td>51</td> <td>97920</td> <td>220</td> </tr> <tr> <td>UPC:</td> <td>Case:</td> <td colspan="4"></td> <td></td> </tr> <tr> <td></td> <td>Carton:</td> <td colspan="4"></td> <td></td> </tr> </tbody> </table>			Item	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width:	Item:	42.29 g		3.23	1.77	5.7171		Box/ Carton:					0		Case:	2.3	11.06	4.18	7.5	346.731	24	Pallet:		48	40	51	97920	220	UPC:	Case:							Carton:					
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Is Item... <input type="text"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> Is it reverse numbered? <input type="text"/>		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		Other Product Information Size/Strength/Form: <input type="text" value="100ct/60mg/Tablets"/> Product Shape: <input type="text" value="Oval"/> Product Color: <input type="text" value="Yellow"/> Product Imprint: <input type="text" value="N 60"/>																																																						
WHOLESALE USE ONLY: Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>				COST INFORMATION <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Regular Cost Per Unit of Sale (\$)</th> <th>Invoice Cost (WAC) (\$)</th> <th>Federal Excise Tax Per Unit of Sale</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align: center;">\$43.50</td> <td></td> </tr> </tbody> </table>		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		\$43.50																																																
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As of date: <input type="text" value="6/26/2015"/>																																																										
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.																																																										
*Please provide any additional information on page 2.		See new p. 3 for Designated Drop Ship Only.		Signature: <input type="text"/>																																																						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine ($\geq 2.2\%$)

Other:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level	How?	GTIN-14
Serialized?	<input type="checkbox"/>	Item	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
If not, when?	<input type="text"/>	Box/ Carton	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Items aggregated to case?	<input type="checkbox"/>	Case	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
		Pallet	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

